

What is Claimed is:

1. Method of monitoring autoantibodies to thyroid stimulating hormone (TSH) receptor in a sample of body fluid, comprising, in the following order, the steps of:
  - (a) providing a TSH receptor selected from the group consisting of:
    - (i) porcine TSH receptor or a fragment thereof immobilized to a solid phase; and
    - (ii) TSH receptor which is complexed to a labelled antibody;
  - (b) incubating said TSH receptor with a sample of body fluid;
  - (c) reacting said incubated sample of body fluid containing said TSH receptor with at least one binding agent which is capable of binding to said TSH receptor in competitive reaction with TSH receptor autoantibodies (TRAb), or when said TSH receptor is (ii), reacting said incubated sample of body fluid, during or after step (b), with at least one binding agent which can bind to TRAb in such a way as not substantially to interfere with binding of said TRAb to said TSH receptor; and
  - (d) qualitatively or quantitatively detecting bound TRAb in said reacted incubated sample of body fluid.
2. Method according to claim 1, wherein said sample of body fluid comprises blood, plasma or serum.
3. Method according to claim 1, wherein said solid phase comprises a plastics material, a magnetic material or a non-magnetic material.
4. Method according to claim 1, wherein said labelled antibody comprises an antibody to TSH receptor.
5. Method according to claim 1, wherein said agent capable of binding to said TSH receptor is selected from the group consisting of TRAb, mouse monoclonal antibodies, human monoclonal antibodies, peptides and recombinant antibodies.
6. Method according to claim 1, wherein said agent capable of binding to said TSH receptor is immobilized to a solid phase.

7. Method according to claim 1, wherein said agent capable of binding to said TSH receptor is labelled isotopically.
8. Method according to claim 7, wherein said isotopic label comprises  $^{125}\text{I}$ .
9. Method according to claim 1, wherein said agent is labelled non-isotopically by means of an enzyme, a dye, or a fluorescent or chemiluminescent material.
10. Method according to claim 1, wherein said porcine TSH receptor is immobilized, either directly or indirectly, to said solid phase, via an antibody to the TSH receptor.
11. Method according to claim 1, wherein said labelled antibody is indirectly labelled with an organic compound.
12. Method according to claim 11, wherein said organic compound comprises biotin.
13. Method according to claim 11, wherein said organic compound is complexed to a protein with an affinity for said compound.
14. Method according to claim 13, wherein said protein is selected from the group consisting of avidin and streptavidin.
15. Method according to claim 1, wherein said porcine TSH receptor is derived from porcine thyroid tissue.
16. Method according to claim 1, wherein said porcine TSH receptor comprises recombinant material with at least one epitope for TRAb.
17. Method according to claim 1, wherein said TSH receptor comprises recombinant or synthetic material with at least one epitope for TRAb.
18. Method according to claim 1, wherein step (d) comprises detecting of labelled or unlabelled TSH bound to TSH receptor and unbound labelled or unlabelled TSH.

19. Method according to claim 18, wherein said labelled or unlabelled TSH comprises bovine or porcine TSH.
20. Method according to claim 1, wherein step (d) comprises detecting of labelled or unlabelled TSH agonist bound to TSH receptor and unbound labelled or unlabelled TSH agonist.
21. Method according to claim 20, wherein said TSH agonist is a monoclonal antibody reactive with said TSH receptor, or a fragment of said monoclonal antibody.
22. Method according to claim 21, in which said monoclonal antibody is a human monoclonal antibody.
23. Method according to claim 21, wherein said monoclonal antibody is a recombinant antibody or recombinant antibody fragment.
24. Method according to claim 20, wherein said TSH agonist is a peptide.
25. Method according to claim 24, wherein said peptide is derived from TSH.
26. Method according to claim 1, wherein step (d) comprises detecting of labelled or unlabelled TSH antagonist bound to TSH receptor and unbound labelled or unlabelled TSH antagonist.
27. Method according to claim 26, wherein said TSH antagonist is a monoclonal antibody reactive with said TSH receptor, or a fragment of said monoclonal antibody.
28. Method according to claim 27, in which said monoclonal antibody is a human monoclonal antibody.
29. Method according to claim 27, wherein said monoclonal antibody is a recombinant antibody or recombinant antibody fragment.
30. Method according to claim 26, wherein said TSH antagonist is a peptide.

31. Method according to claim 30, wherein said peptide is derived from TSH.
32. A kit for monitoring autoantibodies to thyroid stimulating hormone (TSH) receptor in a sample of body fluid, comprising:
- (a) providing a TSH receptor selected from the group consisting of:
    - (i) porcine TSH receptor or a fragment thereof immobilized to a solid phase; and
    - (ii) TSH receptor which is complexed to a labelled antibody;
  - (b) at least one binding agent which is capable of binding to said TSH receptor in competitive reaction with TSH receptor autoantibodies (TRAb), or when said TSH receptor is (ii) at least one binding agent which can bind to TRAb in such a way as not substantially to interfere with binding of said TRAb to said TSH receptor;
  - (c) means for incubating said TSH receptor of (a) with a sample of body fluid;
  - (d) means for reacting said incubated sample of body fluid of (c) with said at least one binding agent of (b); and
  - (e) means for qualitatively or quantitatively detecting bound TRAb in said reacted incubated sample of body fluid.
33. A kit according to claim 32, wherein said sample of body fluid comprises blood, plasma or serum.
34. A kit according to claim 32, wherein said solid phase comprises a plastics material, a magnetic material or a non-magnetic material.
35. A kit according to claim 32, wherein said labelled antibody comprises an antibody to TSH receptor.
36. A kit according to claim 32, wherein said agent capable of binding to said TSH receptor is selected from the group consisting of TRAb, mouse monoclonal antibodies, human monoclonal antibodies, peptides and recombinant antibodies.
37. A kit according to claim 32, wherein said agent capable of binding to said TSH receptor is immobilized to a solid phase.

38. A kit according to claim 32, wherein said agent capable of binding to said TSH receptor is labelled isotopically.
39. A kit according to claim 38, wherein said isotopic label comprises  $^{125}\text{I}$ .
40. A kit according to claim 32, wherein said agent is labelled non-isotopically by means of an enzyme, a dye, or a fluorescent or chemiluminescent material.
41. A kit according to claim 32, wherein said porcine TSH receptor is immobilized, either directly or indirectly, to said solid phase, via an antibody to the TSH receptor.
42. A kit according to claim 32, wherein said labelled antibody is indirectly labelled with an organic compound.
43. A kit according to claim 42, wherein said organic compound comprises biotin.
44. A kit according to claim 42, wherein said organic compound is complexed to a protein with an affinity for said compound.
45. A kit according to claim 44, wherein said protein is selected from the group consisting of avidin and streptavidin.
46. A kit according to claim 32, wherein said porcine TSH receptor is derived from porcine thyroid tissue.
47. A kit according to claim 32, wherein said porcine TSH receptor comprises recombinant material with at least one epitope for TRAb.
48. A kit according to claim 32, wherein said TSH receptor comprises recombinant or synthetic material with at least one epitope for TRAb.
49. A kit according to claim 32, wherein step (d) comprises detecting of labelled or unlabelled TSH bound to TSH receptor and unbound-labelled or unlabelled TSH.

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50. A kit according to claim 49, wherein said labelled or unlabelled TSH comprises bovine or porcine TSH.
51. A kit according to claim 32, wherein step (d) comprises detecting of labelled or unlabelled TSH agonist bound to TSH receptor and unbound labelled or unlabelled TSH agonist.
52. A kit according to claim 51, wherein said TSH agonist is a monoclonal antibody reactive with said TSH receptor, or a fragment of said monoclonal antibody.
53. A kit according to claim 52, in which said monoclonal antibody is a human monoclonal antibody.
54. A kit according to claim 52, wherein said monoclonal antibody is a recombinant antibody or recombinant antibody fragment.
55. A kit according to claim 51, wherein said TSH agonist is a peptide.
56. A kit according to claim 55, wherein said peptide is derived from TSH.
57. A kit according to claim 32, wherein step (d) comprises detecting of labelled or unlabelled TSH antagonist bound to TSH receptor and unbound labelled or unlabelled TSH antagonist.
58. A kit according to claim 57, wherein said TSH antagonist is a monoclonal antibody reactive with said TSH receptor, or a fragment of said monoclonal antibody.
59. A kit according to claim 58, in which said monoclonal antibody is a human monoclonal antibody.
60. A kit according to claim 58, wherein said monoclonal antibody is a recombinant antibody or recombinant antibody fragment.
61. A kit according to claim 57, wherein said TSH antagonist is a peptide.

62. A kit according to claim 61, wherein said peptide is derived from TSH.

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